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APPLICATION NUMBER	FILED DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/040,485	03/17/98	RADOSEVICH	J 8998/3

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EXAMINER

WORRALL, T

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/18/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 03/17/98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire zero month(s), or thirty days whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-18 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-18 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Restriction Fax Transmission

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

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Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1642 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula K. Hutzell, Ph.D., Supervisory Patent Examiner, at Paula.Hutzell@uspto.gov or (703)308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-5, drawn to polynucleotide sequences, classified in class 536, subclass 23.1.
 - II. Claims 6, 7, 9-11, and 17-18 drawn to proteins and peptides, classified in class 530, subclass 350+.
 - III. Claims 12-14, drawn to an antibody, classified in class 530, subclass 387.1+.
 - IV. Claim 8 and 15, drawn to detection methods using DNA hybridization probes, classified in class 435, subclass 6.
 - V. Claim 16, drawn to attenuating the expression of a cDNA molecule, classified in class 536, subclass 24.5.
2. The inventions are distinct, each from the other because of the following reasons:

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3. The proteins compositions of Group I is related to the nucleic acids of Group II since the polynucleotides encode the protein compositions. Although they are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from non-recombinant cells. Further, the DNA may be used for processes other than the production of the protein, such as a nucleic acid hybridization assay. The examination of both groups would require different searches in the U.S. Patent Shoes and the scientific literature, and would require the consideration of different patentability issues.

4. The proteins of Group I are related to the antibodies of Group III by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two compositions, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used for other materially different processes in its own right, such as in a method of treatment, or in assays for the identification of agonists or antagonists for the protein. The examination of both groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

5. The nucleic acid of Group II and the antibody of Group III are different chemical compositions with different chemical properties and different methods of use. The examination

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of both groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

6. The methods of groups VI and V differ in the method objectives, method steps and parameters, and in the reagents used. The objectives of the methods have different endpoints, requiring different searches of the prior art. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

7. Inventions I and (IV and V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide sequence of Invention I can also be used in to express the protein of Invention II.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. This application contains claims directed to patentably distinct species of the Invention II. Specifically, claim 9 is limited to the following patentably distinct species:

- a. The amino acid encoded by the cDNA of FIG. 1;
- b. The amino acid encoded by the cDNA of FIG 2;

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- c. SEQ ID NO:6;
- d. SEQ ID NO:7;
- e. SEQ ID NO:8
- f. SEQ ID NO:9.

Upon the election of Invention II, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the vaccine comprising an amino acid sequence is generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. A telephone call was made to Alice Martin on March 10, 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning the communication or earlier communications from the examiner should be directed to Timothy A. Worrall, Ph.D. whose telephone number is (703) 308-9348. The examiner can normally be reached on Monday through Friday from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-3014.

Communications via Internet-e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paula.hutzell@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements under 35 U.S.C.122. This is more

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clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997, at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Timothy A. Worrall, Ph.D.

March 12, 1999


PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

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COMMENTS: _____

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

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